Z-Medica, LLC
% Yarmela Pavlovic
Partner
Hogan Lovells U.S. LLP
3 Embarcadero Center
Suite 1500
San Francisco, California 94111

April 21, 2023

Re: K181641
Trade/Device Name: QuikClot Radial
Regulatory Class: Unclassified
Product Code: QSY

Dear Yarmela Pavlovic:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 24, 2018. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

December 24, 2018

Z-Medica, LLC
% Yarmela Pavlovic
Partner
Hogan Lovells U.S. LLP
3 Embarcadero Center
Suite 1500
San Francisco, California 94111

Re: K181641
Trade/Device Name: QuikClot Radial
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 30, 2018
Received: November 30, 2018

Dear Yarmela Pavlovic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K181641

Device Name

QuikClot® Radial®

Indications for Use *(Describe)*

QuikClot® Radial® is applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 7 Fr. in (a) patients on drug/induced anti-coagulation treatment and (b) patients not on drug/induced anti-coagulation treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K181641

510(k) SUMMARY

Z-Medica, LLC's QuikClot® Radial®

Submitter

Z-Medica, LLC
4 Fairfield Boulevard
Wallingford, CT 06492

Phone: 203-774-7922
Facsimile: 800-406-1347

Contact Person: Sheila K. Wallin, U.S. Regulatory and Clinical Affairs Advisor

Date Prepared: December 21, 2018

Name of Device: QuikClot® Radial®

Common or Usual Name: Hemostatic dressing

Classification Name: Unclassified (Pre-Amendments)

Regulatory Class: Unclassified

Product Code: FRO

Predicate Device: Z-Medica, LLC's QuikClot® Interventional-A Hemostatic Bandage (K120782)

Reference Device: Z-Medica, LLC's QuikClot® Interventional Dressing (K090620)

Device Description

The QuikClot® Radial® consists of a rolled hemostatic dressing to be used in conjunction with Tegaderm™, Coban™, or equivalent adhesive bandage (not supplied). The roll is a soft, white, sterile, hydrophilic, kaolin-impregnated gauze. Kaolin is a hemostatic agent that functions to stop bleeding in anti-coagulated patients, and is used in the same form and amount as in the predicate device. The kaolin is bound to the gauze in the same manner as in the predicate device. The QuikClot® Radial® is configured in 0.75" diameter x 1.5" length. The device is packaged for aseptic removal in a peelable foil pouch. The dressing is a single-use device that has surface contact with breached or compromised skin for a limited duration (≤24 hours).

The QuikClot® Radial® has been tested in clinical trials and its efficacy has been shown, for patients on anti-coagulants, only in those treated with the anti-coagulant medications: heparin, Clopidogrel bisulfate, and warfarin. The efficacy of QuikClot® Radial® in the presence of other anti-coagulants is not known. The QuikClot® Radial® has not been tested on patients with bleeding disorders due to underlying disease (liver, kidney, or others) and is not indicated for these populations.

Intended Use / Indications for Use

The QuikClot® Radial® is applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 7 Fr in (a) patients on

drug/induced anti-coagulation treatment and (b) patients not on drug/induced anti-coagulation treatment.

Summary of Technological Characteristics

Hemostasis through the presence of a hemostatic agent (kaolin), in conjunction with compression, is the technological principle for both the subject and predicate devices. The QuikClot® Radial® and its predicate device have nearly identical technological characteristics:

- Both devices consist primarily of a multi-layer hemostatic pad/roll made of soft, kaolin-impregnated gauze.
- Both devices are made of exactly the same materials.
- Both devices are applied topically directly to the site of bleeding.
- Both devices are used as adjuncts to the application of pressure at the puncture site, to bolster the cessation of bleeding through the hemostatic effect of the kaolin in the gauze.

The following technological differences exist between the subject and predicate devices:

- The subject device is provided in a tube shape (0.75” diameter x 1.5” length) rather than the rectangular shape of the predicate (1.5” length x 1.5” width, approximately 0.5” thick), and is slightly larger than the predicate (rolled out, the predicate measures 1.5” x 43”, whereas QuikClot® Radial® measures 1.5” x 50”).
- The subject device is not supplied with an adhesive bandage.

Performance Data

As the QuikClot® Radial® is nearly identical to the cleared predicate device, no new bench, animal, or biocompatibility testing was performed in support of this submission. The previous test results remain applicable.

Clinical data submitted in support of the predicate device’s 510(k) clearance remains applicable and is incorporated in this submission, as the difference in geometric configuration has no impact on the safety of the product or the associated clinical outcomes. Two additional confirmatory clinical studies were performed by the company to assess the hemostatic bandage’s use specifically at transradial access sites further confirmed its safety and efficacy. Subjects were selected from a diverse pool that is representative of the patient population for which the device will be marketed.

- Study 1: 30 patients, both male and female, ages ranging from ~53-82, undergoing transradial diagnostic coronary angiography and/or interventional coronary procedures via the radial artery, were randomized into cohorts treated with either the subject device or a standard of care.

- Study 2: 20 patients, both male and female, ages ranging from ~49-80, undergoing cardiac catheterization and/or percutaneous coronary intervention via the radial artery, were randomized into cohorts treated with the subject device using different secondary bandages.

All patients treated with the QuikClot® Radial® dressing achieved successful hemostasis without occurrence of re-bleeding or radial artery occlusion. No major complications were reported in either study. In addition, in the first study, mean time to achieve successful hemostasis was

significantly shorter for patients treated with the QuikClot® Radial® than for those treated with the standard of care at the institution (TR Band). Based on the clinical performance, the QuikClot® Radial® has a safety and effectiveness profile that is similar to the predicate device and thus substantially equivalent.

Conclusion

The QuikClot® Radial® is as safe and effective as the QuikClot® Interventional-A Hemostatic Bandage (K120782). QuikClot® Radial® has the same intended use and principles of operation, and very similar indications for use and technological characteristics, as its predicate device. The minor differences between the QuikClot® Radial and its predicate do not alter its therapeutic purpose or raise new issues of safety or effectiveness, and performance data demonstrate that QuikClot® Radial® is as safe and effective as the predicate device. Thus, the QuikClot® Radial® is substantially equivalent to the QuikClot® Interventional-A Hemostatic Bandage (K120782).